K100631

Summary of Safety and Effectiveness

JUN 22 2010

I. Applicant Information:

Date Prepared:	June 21, 2010
Submitter:	Medtronic, Inc. Medtronic Perfusion Systems
Address:	7611 Northland Drive Minneapolis, MN 55428
Establishment Registration No.:	2184009 (owner operator number 2112641)
Contact Person:	Sue Fidler, Regulatory Affairs Manager Medtronic, Inc. 8200 Coral Sea Street NE Mounds View, MN 55112
Telephone Number: Fax Number:	(763) 514-9839 (763) 367-8360

II. Device Information:

Trade Name:	Medtronic AFFINITY™ CP Centrifugal Blood Pump (Model AP40); Medtronic External Drive Motor (Model 560A); Medtronic Emergency Handcrank (Model HC150A)
Common Name:	AFFINITY™ Cardiopulmonary Centrifugal Blood Pump; External Drive Motor; Emergency Handcrank
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type; Cardiovascular bypass pump speed control
Classification:	Class III, 21 CFR 870.4360; Class II, 21 CFR 870.4380
Product Code:	KFM; DWA
Predicate Devices:	Medtronic Bio-Medicus® Bio-Pump (BPX-80) Centrifugal Pump (K973011); Medtronic External Drive Motor (Model 540T) (K936091); Emergency Handcrank (Model H150) (K926357)

Predicate Device Intended Uses:

The BPX-80 centrifugal blood pump is indicated for use only with the Medtronic Bio-Console pump speed controller to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours).

It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants).

The External Drive Motor and Emergency Handcrank are intended for use with the Bio-Console System and Bio-Pump Centrifugal Blood Pump. The Bio-Console System is a centrifugal blood pumping system intended for use as an extracorporeal centrifugal blood pumping system during cardiopulmonary bypass procedures.

Device Description: The Medtronic AFFINITY CP Centrifugal Blood Pump is a sterile, single-use centrifugal blood pump. It is a non-invasive, non-pyrogenic device designed to move blood through the extracorporeal circuit by centrifugal force. The pump is the disposable portion of the pumping system and it is electromagnetically coupled to an instrument that monitors and displays the flow and pressure of the blood. Blood enters the inlet port of the pump, where a cone with impeller blades within the pump housing rotates and the blood is gently accelerated towards the outlet of the pump.

The AFFINITY CP Centrifugal Blood Pump can be driven through magnetic coupling by the following two devices:

- External Drive Motor (Model 560A)
- Emergency Handcrank (Model HC150A)

Intended Use: *The AFFINITY™ CP Centrifugal Blood Pump is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours).*

It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardiopulmonary bypass (eg, valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants)."

The AFFINITY™ CP Centrifugal Blood Pump is driven by the External Drive Motor or the Emergency Handcrank.

Contraindications: The AFFINITY CP Centrifugal Blood Pump is contraindicated as a cardiotomy suction device.

Comparison to Predicate Device: The AFFINITY CP Centrifugal Blood Pump is substantially equivalent to the predicate device, in that its intended use is the same, and the basic design is the same, with a magnetic coupling to an external motor that drives the rotating cones. Both pump drives are controlled with Medtronic controllers. The new pump includes the following improvements:

- The bearing heat generation is reduced due to a ceramic pivot system.
- Priming volume is reduced by 50%, to a volume of 40 mL.
- Hemolysis is reduced compared to the predicate device.

The External Drive Motor and Emergency Handcrank are substantially equivalent to the predicate devices, in that their intended uses are the same and the basic design is the same. Necessary design changes were made to allow for compatibility with the AFFINITY CP Centrifugal Blood Pump: dimensional changes and rotational direction.

Test Data: Verification and validation testing has demonstrated that the AFFINITY CP Centrifugal Blood Pump and its associated drive systems are safe and effective. The blood pump is more efficient, as evidenced by less heat generation, and less damaging to red blood cells, as evidenced by reduced hemolysis. Other validation tests included: maximum pressure generation, flow rates, pivot bearing wear, maximum speed, port strength, magnetic coupling force, biocompatibility, noise generation and prime volume. Validation testing under simulated conditions of use with expert users also demonstrated the effectiveness of the AFFINITY CP Centrifugal Blood Pump.

Summary: Based on the accumulated technical information, intended use, laboratory verification tests and performance data provided, the AFFINITY CP Centrifugal Blood Pump and its associated drive systems are substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUN 22 2010

Medtronic, Inc.
c/o Ms. Susan C. Fidler
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K100631
Trade/Device Name: Medtronic AFFINITY™ CP Centrifugal Blood Pump (Model AP40); Medtronic External Drive Motor (Model 560A); Medtronic Emergency Handcrank (Model HC150A)
Regulation Number: 21 CFR 870.4360
Regulation Name: Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class: III
Product Code: KFM, DWA
Dated: May 24, 2010
Received: May 25, 2010

Dear Ms. Fidler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K100631

Medtronic AFFINITY™ CP Centrifugal Blood Pump (Model AP40); Medtronic External Drive Motor (Model 560A); Medtronic Emergency Handcrank (Model HC150A)

Indications for use:

The AFFINITY™ CP Centrifugal Blood Pump is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours).

It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants).

The AFFINITY™ CP Centrifugal Blood Pump is driven by the External Drive Motor or the Emergency Handcrank.

Prescription Use ___x___ **OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman 6/22/2010

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K100631